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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,418	03/01/2002	David A. Edwards	2846.1001-028	8180

7590 01/28/2004

Elmore Craig P C  
209 Main Street No  
Chelmsford, MA 01863

EXAMINER

KIM, JENNIFER M

ART UNIT PAPER NUMBER

1617

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/090,418

Applicant(s)

EDWARDS ET AL.

Examiner

Jennifer Kim

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 4-11, 19-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-11 and 19-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

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### DETAILED ACTION

The amendment filed on October 28, 2003 have been received and entered into the application.

#### *Response to Arguments*

Applicants' arguments filed on October 28, 2003 have been fully considered but they are not persuasive. Applicants argue that the claims of the instant invention disclose a method of increasing systemic bioavailability of a hormone administered by inhalation comprising aerodynamically light particles having a mass mean diameters grater than 5um, a stated aerodynamic diameter wherein the particles are delivered and deposited to the lung and the hormone is release in the blood stream for at least 4 hours, but there is nothing in Platz that teaches such a release profile and Platz repeatedly sates that the desired size range, i.e., below 5 um, and preferably in the range from 0.4um to 5 um. This is not persuasive because as asserted by the Applicants that Platz **does mention** compositions having a particle size below 10 um (Col. 6, line 5). Therefore, this teaching alone would motivate one of ordinary skill in the art to employ any particle size below 10 um including Applicants' claiming particle of diameter of greater than 5 um upto 10um. Absent any evidence to contrary, there would have been a reasonable expectation of successfully achieving formulating a

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delivery composition as taught by Platz. Applicants' recitation of time period, which the hormone is released, would obviously be achieved upon the composition having a particle size below 10  $\mu$ m. Absent any evidence to the contrary there would have been a reasonable expectation of successfully achieving increased systemic bioavailability of hormone administered by inhalation of the same composition taught by the prior art. It is noted that Applicants' instant claims do not represent a patentable limitation to impart any physical limitation to the prior art composition.

It is suggested, to advance the prosecution of the subject application, that a side by side comparison of bioavailability be performed and results submitted per Rule 1.132 for review by the Patent Office.

In view of the above Office Action of July 29, 2003 is deemed proper and asserted with full force and repeated herein to obviate applicants' claims.

### *Double Patenting*

Claims 1, 4-5, 14 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 16, 17 of U.S. Patent No. 5,874,064.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims encompass the instant claims since they are directed to any therapeutic agent. Moreover insulin is enumerated in the specification of the patent as one of the therapeutic agents, see col. 10, lines 36-47 in particular.

Claims 1, 2, 4, 7-11<sup>+19-21</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 17, 20+27 of U.S. Patent No. 5,855,913. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the patented claims overlaps with the instant claims. The instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is between 1-3 microns the claims overlap.

Claims 1, 2, 4-11<sup>+19-21</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-20, 23 and 26<sup>+1</sup> of U.S. Patent No. 6,436,443. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims overlap with the instant claims in so far as a MMD of between 6 and 30 microns is claimed and an aerodynamic diameter of between 1-4.6999 microns is claimed

Claims 1, 2, 4, 5, 7-11<sup>+19-21</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 and 22 of U.S. Patent No. 5,985,309. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 5.1-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is between 1-4.6999 microns the claims overlap.

Claims <sup>1, 2, 4, 10-11, 19-21</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 20-21 of U.S. Patent No. 6,503,480 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is concerned in so far as the particles are between 1 micron and 4.6999 microns the claims overlap, see also example 7 and column 16.

Claims <sup>1-2, 4-11, 19-21</sup> are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 15-16 and 26-27 of U.S. Patent No. 6,254,854. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims recite a MMD greater than 5 microns while the patented claims recite a MMD between 5-30 microns therefore as to particles having a MMD of between 6-30 microns the claims overlap. Also, in so far as the particles aerodynamic diameter is concerned in so far as the particles are between 1 micron and 4.6999 microns the claims overlap, see also example 7 and column 16.

#### *Claim Rejections - 35 USC § 103*

Claims <sup>1, 2, 4-11 + 19-21</sup> are rejected under 35 U.S.C. 103(a) as being unpatentable over Platz et al. (USPN 6,423,344 B1).

Platz et al. (USPN 6,423,344 B1) teaches a method of delivering therapeutic agents such as insulin along with pharmaceutical carriers and excipients to the lung of a patient particles having a mass mean diameter of less than 10 microns and particles having a diameter of 0.4-5 microns, see claims 1,4-6, 13 and col. 6, line 38 to col. 8 line 21, col. 9, lines 11-67 and Tables 2-3, for example.

Platz does not does not particularly teach the release profile of the insulin composition employed in its method, neither does it teach mass mean diameter greater than 20 microns.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to increase the mass mean diameter of the particles. It would have also been obvious to recite the instant release profiles in the claims.

One of ordinary skill in the art would have been motivated to increase the mass mean diameter of the particles because employment of larger particles in a pulmonary inhalation method is known in the art. Note that the same composition, administered in the same manner would be reasonably expected to exhibit the same release profile.

With regard to the specified tap density set forth in claims 19-21 would be a property of the particle employed in the prior composition comprising very same particle with very same size. Therefore the prior art composition would possess same tap density as claimed by the very same particle employed by the Applicants.

None of the claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

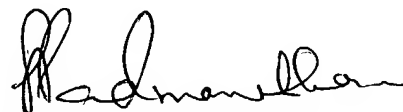
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 703-308-2232. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



Sreenivasan Padmanabhan  
Supervisory Examiner  
Art Unit 1617

Jmk  
January 23, 2004

1/24/04